

## **REMARKS**

### **Status of the Claims**

Claims 12, 14, 15, 17, 21, 22, 26, 30 and 32-34 are now present in this application. Claim 12 is independent. Claims 31-34 have been added as supported by e.g., page 10, lines 1-11 of the present specification. Thus, no new matter has been added.

Reconsideration of this application is respectfully requested.

### **Issue under 35 U.S.C. §103(a)**

Claims 12, 14, 15, 17, 21, 22, 26 and 30 stand rejected under 35 U.S.C. §103(a) as being unpatentable over De La Torre et al. (Reviste Italiana Di Nutrizione Parenterale ed Enterale, Vol. 21, No. 3, pp 105-111, Wichig Editore, Mila, IT, January 1, 2003), in view of Bijlsma (WO 00/57727). This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

### **The Present Invention**

The present invention is directed to a method for ameliorating or treating an inflammatory bowel disease (IBD), comprising administering a composition comprising galactomannan in an amount sufficient to lower the activity of myeloperoxidase and TNF- $\alpha$  to a patient suffering from said IBD, wherein said galactomannan is a degraded galactomannan having an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5 (w/v)% aqueous solution of the degraded galactomannan, wherein the degraded galactomannan is produced by hydrolyzing guar gum with  $\beta$ -mannanase without further chemical processing, and wherein the administering step includes administering the composition having 5-100% by weight of galactomannan in an amount of 1 to 70g/day/adult (emphasis added).

Distinctions Over the Cited Art

As recited in claim 12, the present composition requires at least a specific degraded galactomannan which has an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5(w/v)% aqueous solution of the degraded galactomannan, and is produced by hydrolyzing guar gum with  $\beta$ -mannanase without further chemical processing.

In contrast, Bijlsma discloses slightly negatively charged non-digestible polysaccharides wherein the chemical modification (i.e., introduction of carboxy, sulphate or phosphate group which is negatively charged at pH 5.5-7) is made to natural polysaccharides. Example 1 of Bijlsma shows that hydrolyzed guar gum is subjected to further modification by addition of pyridine sulphur trioxide. Also, as illustrated in Fig. 2, carboxydextrans to which carboxy group is introduced present excellent inhibition of carbachol induced permeability for Horseradish peroxidase (HRP) as compared to neutral dextrans (see CDH 150 v.s. Dcx 150 and CDI-1 69 v.s. Dex69). That is, Bijlsma notes that neutral polysaccharides having no carboxy group do not exhibit any effects intended by Bijlsma. Accordingly, in Bijlsma, such further chemical modification is critical to more effectively reduce transport via the tight junctions of the intestines.

Whereas, the present method includes at least the feature of "without further chemical processing" as defined in claim 12, and thus, the chemical modification taught by Bijlsma is not made to the degraded galactomannan of the present invention. Specifically, the present method does not require introduction of the negatively charged carboxy or sulphate group into guar gum. Instead, the present invention obtains the claimed degraded galactomann by enzymolysis. In other words, the present degraded galactomann is produced by hydrolyzing guar gum with  $\beta$ -mannanase without further chemical processing.  $\beta$ -mannanase is derived from bacterium of *Aspergillus* or *Rhizopus*. Also, such hydrolysis is performed at a temperature of 10 to 80°C for about 1 to about 75 hours. Accordingly, it is not necessary for the present method to incorporate chemical step or process for introducing chemical groups into the galactomannan as in Bijlsma. Based on these, even in consideration of Bijlsma requiring chemical modification, a person skilled in the art would be never motivated to achieve the present invention. Therefore, the

degraded galactomann of the present invention is different from that of Bijlsma.

Also, the primary reference of De La Torre discloses a partially hydrolyzed guar gum (PHGG). However, the molecular weight and viscosity thereof are not taught by De La Torre, as admitted by the Examiner. Thus, even if the cited references were to hypothetically be combined with each other, they still cannot achieve the present invention. Further, the method of Bijlsma discloses that transport via the tight junctions of the intestines is effectively reduced by further chemical modification. Bijlsma shows that polysaccharides without chemical modification do not reveal intended effect (see Fig. 2 of Bijlsma). On the other hand, the PHGG of De La Torre does not require introduction of negatively charged group. In Bijlsma, without introduction of such group, inferior results occur. Thus, teachings of Bijlsma are clearly taught away from those of De La Torre requiring no introduction of carboxy group. Therefore, a skilled artisan would not combine Bijlsma with De La Torre. And, even if combined, there would be no expectation of success since Bijlsma teaches inferior results when polysaccharides do not have chemical modification.

Further, the cited art individually or in combination fails to disclose or suggest the present hydrolysis conditions recited in claims 32-34.

For at least the reasons set forth above, reconsideration and withdrawal of the obviousness rejection are respectfully requested.

### **Conclusion**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejection and that it be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

In view of the above remarks, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Registration

No. 42,874, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: OCT 14 2011

Respectfully submitted,

By

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